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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: American Forest & Paper Association Comments on Proposed Regulations for Registration of Food Facilities FDA Docket No. 02N-0276

Dear Sir or Madam:

These comments are submitted by the American Forest & Paper Association (AF&PA), the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents member companies engaged in growing, harvesting, and processing wood and wood fiber, manufacturing pulp, paper, and paperboard products from both virgin and recycled fiber, and producing engineered and traditional wood products. AF&PA members include manufacturers of over eighty percent of the paper, wood, and forest products produced in the United States. Because virtually all of the packaging and packaging component facilities of the member companies—as well as all of their suppliers—would be required to register under the proposed regulation, AF&PA is submitting these comments to ensure that the Food and Drug Administration (FDA) considers the full impact of its proposed regulations on the industry.

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The regulations as drafted will impose a very large burden on AF&PA member companies, with only a very limited and theoretical increase, if any, in the safety of the food supply. In proposing that the registration requirements apply to packaging material and other food contact article facilities, FDA has not followed the express intent of Congress, and has created an unreasonable and unjustified burden on the industry and its suppliers. FDA must follow the explicit language of the statute, and give effect to each word therein.

Section 305 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) provides that FDA shall by regulation "require that any facility engaged in manufacturing, processing, packing or holding food for consumption in the United States be registered [with FDA]." (Emphasis added.) Congress clearly modified "food" with the term "for consumption" in describing facilities that are subject to the registration requirement. FDA has ignored this explicit language, in direct contravention to the well established principle that each word in a statute has significance. FDA's proposed definition includes only "food," and wrongly ignores the qualifying phrase "for consumption." This incomplete definition would require not only AF&PA members to register their facilities, but also all their suppliers. With FDA's incomplete definition, there is no limit to the suppliers of components and precursor substances who would be required to register. Every reclaimed fiber depot would also be included. FDA should correct this flawed definition, and replace it with a definition of "food for consumption" for purposes of the registration provisions, thus excluding packaging materials and other food contact articles. Doing so is consistent with the clear language of the authorizing legislation and FDA's mandate to ensure the safety of the United States food supply in the least burdensome means possible.

I. FDA's Proposed Inclusion of Food Packaging and Other Food Contact Substances in the Definition of "Food for Consumption" is Not Consistent with Congressional Intent

Section 305 of the Bioterrorism Act requires registration of any facility engaged in manufacturing, processing, packing or holding "food for consumption" in the United States. Because the statute requires registration only for facilities engaged with "food for consumption in the United States," manufacturers of food packaging and other food contact articles were not concerned that this requirement could be applied to anything other than food that is actually consumed. It was thought that FDA would abide by the statutory language that requires application of this provision only to food that is actually consumed.

For purposes of its proposed regulations, FDA has inexplicably defined only "food" rather than the phrase used in the statute: "food for consumption." In direct opposition to the explicit statutory language, the FDA proposed definition would encompass all articles within its statutory jurisdiction under 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), rather than limit the scope of the registration provision to the articles specifically included by Congress: "food for consumption." FDA provides examples of products that are technically considered "food" under the FD&C Act, including "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. 5378, 5382 (February 3, 2003). If FDA is permitted to ignore the express language of the enabling statute, there is no obvious limit to the facilities to which it could apply the registration requirement. Any facility engaged in the manufacture, processing, packing, or holding of any component or precursor substance of food packaging or any other food contact material would be subjected to the registration requirement, as any ingredient of an ingredient of

something that may migrate into food is considered a "food" under FDA's interpretation. But none of these components or substances is a "food for consumption."

FDA's proposed registration requirement, when applied to food packaging or other food contact material facilities, will have no benefit for the safety of the food supply. Section 305 of the Bioterrorism Act states that FDA may, through guidance, require the category of food (as defined in 21 C.F.R. 170.3) the facility handles to be included on the registration. There is no category for food packaging or other food contact articles and their components. This is yet further evidence that Congress did not intend packaging and other food contact articles to be included in the definition of "food for consumption" for purposes of the registration requirement.

In a small attempt to exclude articles that have absolutely no food contact, FDA states in the preamble that "Substances that migrate into food from food packaging include immediate food packaging or components of immediate food packaging that are intended for food use. Outer food packaging is not considered a substance that migrates into food." 68 Fed. Reg. 5382. Previously, FDA has required not only physical separation, but also proof of a functional barrier that prevents migration of any component to be satisfied that an outer layer and its components will not migrate to food. Unless FDA is suggesting here that it is changing this longstanding position, this exclusion may be more properly stated as "outer packaging separated from food by a functional barrier is not considered a substance that migrates into food." But this exclusion accomplishes nothing. Packaging components that cannot reasonably be expected to migrate into food are not within FDA's jurisdiction and thus does not even need to be excluded. Despite this "exclusion," tens of thousands of chemicals and food contact articles will be required to be manufactured in a registered

facility. Most facilities manufacture both food use and non-food use materials, resulting in a registration requirement for virtually all facilities that manufacture packaging and packaging components operated by AF&PA members, and all of their suppliers, under FDA's proposed definition.

Congress directed that FDA should exercise "discretion in the development and implementation of registration regulations to ensure that registration requirements are neither burdensome nor disruptive of the smooth flow of commerce." 148 Cong. Rec. H2858 (daily ed. May 22, 2002) (statement of Rep. Shimkus). Imposing the registration requirement on facilities beyond the "food for consumption" scope mandated by Congress clearly violates this congressional instruction.

As the agency authorized to implement the provisions of the Bioterrorism Act, FDA has discretion in interpreting the terms in that legislation. FDA is bound, however, by the language of the statute and clear expressions of congressional intent. When Congress has spoken directly to an issue, the agency (and any reviewing court) must give effect to the unambiguously expressed intent of Congress. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984); *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120, 126 (2000). Here, Congress specifically included the language "for consumption" to qualify "food." FDA has simply defined the wrong word. It should define "food for consumption," not "food."

FDA's proposed inclusion of food packaging and food contact materials in the definition of "food" for purposes of the registration requirement ignores the statutory language. Packaging and other

food contact articles are, quite simply, not consumed. It is well settled that statutes should be interpreted in a manner to give effect to all words in the statute. FDA should replace its definition of "food" with a definition of the statutory terms "food for consumption," and thus exclude items such as food packaging and food contact articles, which may technically fall within the statutory definition of "food," but clearly are not intended "for consumption.

II. Inclusion of Food Packaging and Other Food Contact Materials is Not Consistent with FDA's Food Security Preventive Measures Guidance

In January 2002, FDA issued Draft Guidance for food establishments to implement security measures intended to protect the nation's food supply. CFSAN, Draft Guidance: Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance (January 9, 2002). In that guidance, FDA recognized the insignificance of food packaging and other food contact articles in protecting against intentional attacks on the food supply. This Draft Guidance for industry on measures to increase the security of the food supply was directed at conventional food facilities. No mention was made of packaging facilities. In fact, packaging was mentioned merely as one of the items for which the conventional food facility should establish procedures.

FDA announced the issuance of its Final Guidance with a notice in the Federal Register. 68 Fed. Reg. 13931 (March 21, 2003). In the Final Guidance, FDA goes even further in separating "packaging" from "food," mentioning packaging only in the operations section. The Final Guidance suggests that a conventional food establishment develop procedures to ensure that "only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators" be used for food packaging and that food establishments inspect incoming

materials, including packaging. Final Guidance, p. 10. Clearly, FDA has itself demonstrated that packaging and food are two separate things.

The Final Guidance recommends that the food establishment evaluate the incoming packaging for the possibility of any threat to public health. Thus, if the food establishment follows the FDA Final Guidance, any possible threat to the food supply from the packaging or other food contact material will already be identified by the food establishment, well before the material ever contacts food. This Final Guidance demonstrates that there is no need to apply the registration requirement to facilities that manufacture food packaging and other food contact articles as FDA proposes in these regulations.

AF&PA submitted comments to FDA on March 6, 2002 endorsing the initial Guidance and its correct distinction between food establishments and food packaging suppliers, their components, and ingredients. At no time in the preparation and commenting on the Guidance did the food industry suggest a change in this distinction, or consider it a need for its implementation of security procedures proposed in the Guidance. If this separation were not considered appropriate by our customers or FDA, the comments of AF&PA would have provoked a rebuttal or clarification that was not made by either.

III. Subjecting Food Packaging and Food Contact Substances and Articles to Registration Will Not Further the Purposes of the Bioterrorism Act

The Conference Report on the Bioterrorism Act states that the intent of the bill is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 107 (May 21, 2002). Thus, all the requirements imposed by the Act must be directed at achieving this goal. While many of the provisions of the Bioterrorism Act, when applied to conventional food, will further this purpose, they will not do so when applied to food packaging and other food contact materials.

The potential list of food contact articles is tremendous. For example, if one reviews the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, the scope of the substances that FDA considers "food" under the statute becomes clear. These sections do not cover articles typically referred to as "housewares," which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments. These items have traditionally been considered outside the scope of FDA's food additive authority, but are still "food" under the FD&C Act. Because FDA incorrectly defined "food" rather than "food for consumption" in the proposed regulations, all facilities manufacturing, processing, packing, or holding these articles, and all of their components and precursor substances, require registration. Thus, all firms engaged in any of these industries would be subject to registration: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, and utensils. None of these is "food for consumption."

Applying the registration requirement to this broad variety of products will overwhelm both industry and FDA resources, with no benefit as far as increased security for the United States food supply. It is absurd to believe that a terrorist attack on the food supply will be carried out through

packaging. As a technical matter, it would be virtually impossible to insert a poison in packaging with a sustained release mechanism to contaminate food, without the full cooperation of the packaging manufacturer. Even putting aside the technical and logistical complexities that would be involved, such an indirect approach would have virtually no impact before discovery. Packaging manufacturers and food processors have routine procedures in place to ensure that their packaging materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage.

FDA's proposed registration requirement, when applied to food packaging and other food contact material facilities, will have no benefit for the safety of the food supply. Section 305 of the Bioterrorism Act states that FDA may, through guidance, require the category of food (as defined in 21 C.F.R. 170.3) the facility handles to be included on the registration. There is no category for food packaging. FDA has stated in public meetings that one of the purposes of the registration requirement is to allow FDA to notify facilities engaged in a particular food sector of a threat to that sector. Robert Lake, FDA Satellite Video Conference (January 29, 2003). This simply does not apply to packaging and other food contact material facilities. If, for example, FDA were to receive credible information of a threat to the potato chip supply, FDA would notify the potato chip manufacturers. FDA would not, and should not, attempt to identify the facilities engaged in the manufacture, processing, packing or holding of potato chip packaging. That would be both ineffective and an absurd waste of FDA's valuable resources. Whenever it would be relevant for a food packaging facility to be contacted, it will be because a conventional food is involved. Conventional food facilities necessarily maintain records regarding their suppliers, including packaging and other food contact material suppliers, and the processor would notify their suppliers

or provide the information to FDA at that time. There is no benefit to FDA maintaining an independent database of these facilities.

IV. FDA Underestimates the Burden of the Proposed Regulation

In estimating the cost of the registration requirement, FDA focused on firms in several primary industries. Within these industries, FDA estimates that 22,000 facilities will be required to register. 68 Fed. Reg. at 5391. FDA's estimate, however ignores several aspects that result in an underestimate of the burden imposed. The first is the wide range of "upstream" manufacturers that make ingredients and components that go into food packaging and other food contact articles. Given FDA's willingness to extend the definition of food beyond the clearly expressed congressional intent to everything that may possibly be considered food, any ingredient of any of these items could subject the facility from which it came to registration. For example, the entire chemical industry and all of their distributors and suppliers would be included. This paperwork and logistical burden will be immense, with no commensurate increase in safety of the United States food supply.

The second is the fact that most of the AF&PA member facilities produce both food and non-food use products. Because the registration requirement is for the entire facility, any facility that produces any food use material would be required to register. Thus, FDA's use of a percentage based on estimates of amount of product used with food is invalid. As the registration requirement is proposed, virtually every facility, and the facilities of the suppliers to those facilities, will be required to register.

And third, with FDA's proposed requirements for updating the registration within thirty days of any change in the information on the registration, coupled with the extensive list of information required for the registration, FDA is essentially creating a monthly registration requirement. It is entirely foreseeable that at least one element of the information on the registration could change each month, thereby necessitating an update to the registration. Also, given the requirement to update within thirty days, all companies must review their registration at least once every thirty days to ensure the information remains accurate. This will impose an immense burden in personnel-hours, and one that was not accurately captured in the proposal.

This immense burden will not fall only on large paper, packaging, and chemical suppliers. Many of the facilities are small independent establishments. The recycling industry will also be affected, because many food contact articles make use of recycled input. This would include all curbside recycling programs, which are clearly sources of raw materials for food packaging. Taking FDA's incorrect definition, any facility that manufactures, processes, packs, or holds a material that could become a component of packaging or other food contact article would be required to register. And any supplier of ingredients to manufacturers of any of these items would be required to register. There is no logical end to this chain, which is why Congress wisely inserted one into the legislation: "food for consumption". Only facilities that manufacture, process, pack, or hold food <u>for consumption</u> must register. Because the burden of this legislation could vastly outweigh the benefits unless reasonable limits are imposed, Congress wisely limited the registration requirement. FDA is underestimating the burden it will impose by ignoring that language in its proposal.

FDA is also not considering the cost of the production time lost while all these records are prepared, verified, and provided up and down the supply chain. All customers at any stage will require verification all the way back up the supply chain that all required registrations are in place. AF&PA member companies have already received word from customers that the customers will require the AF&PA member to verify all registration for all inputs of the product sold to the customer. Even though FDA has stated that each facility is only liable for its own registration, this ignores the reality in the marketplace, which is that the entire supply chain must be verified at each stage.

Given the extraordinarily high cost of this proposal, FDA should focus its resources where there is the opportunity to benefit the safety of the United States food supply—conventional food itself. There is no benefit to applying the registration requirements to food packaging and other food contact article facilities, and doing so amounts to nothing more than a waste of limited resources. FDA has been tasked with an immense obligation, ensuring the safety of the United States food supply, and it must focus its resources on areas where the expenditure of resources will yield returns in increased safety. Registration of food packaging and other food contact article facilities will not achieve this purpose.

The examples of foodborne outbreaks that could be averted by these requirements, to which FDA refers in the preamble, have nothing to do with food packaging. Beginning on page 5409 of the preamble, FDA sets out the cost of five foodborne outbreaks. The "vehicles" for these outbreaks are all conventional foods, and have nothing to do with packaging or other food contact articles. If FDA seriously thinks that food packaging or other food contact articles pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack, and

they would have shown that these provision will minimize that risk, in an attempt to justify the immense burden being placed on the industry. FDA has provided no such cost minimization justification. FDA has simply stated that it feels compelled to implement the Bioterrorism Act in this fashion, even though the cost is immense. While FDA must accurately implement the Bioterrorism Act, this proposed regulation goes too far, and—in direct violation of the statutory language—imposes a burden without a proper estimate of the benefit or any cost minimization achieved by the proposal. In the absence of such an estimate, FDA's treatment of food packaging and other food contact materials is completely unjustified.

FDA should replace its erroneous definition of "food" with an accurate definition of "food for consumption" and thus exclude food packaging and other food contact articles as they are clearly not "food for consumption." Doing so is consistent with the statute and the congressional intent, as well as FDA's mission to protect the safety of the United States food supply under the Bioterrorism Act.

Respectfully submitted,

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